

Message

From: Jesse C. Dresser [jdresser@FrierLevitt.com]
Sent: 5/17/2021 2:52:14 PM
To: Martha M. Rumore [mrumore@frierlevitt.com]; Maureen Varco [mvarco@frierlevitt.com]; Lucas Morgan [lmorgan@frierlevitt.com]
Subject: Re: Important FW: FDA communications

Martha:

Appreciate those observations. I see that the FDA call got rescheduled until Wednesday (which is good). I have a call set up with the client today to discuss the subpoena they received. Can you touch base with Maureen to get added to that call? I would like to go over these observations with them on the call today. In addition, can you review the timing of the advice we gave and when they responded (so we can cover our end, as we would have advised differently had they keyed us in fully at the right time).

Jesse C. Dresser, Esq.

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From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Monday, May 17, 2021 10:26 AM
To: Jesse C. Dresser <jdresser@FrierLevitt.com>
Subject: Important FW: FDA communications

Hi Jesse:

I went through the information Safe Chain provided for FDA 3911-45802703 (involving 177 bottles) and FDA many have several reasons for wanting to speak to them. My observations:

**GOVERNMENT
EXHIBIT**

324

1:24-cr-20255-WPD

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Question 4. FDA asked for a list of all dispensers (both name and location) who have quarantined product- Safe Chain did not provide this and stated only a "few customers" returned inventory and those pieces are included in the quarantine report. The needed to account for the 177 bottles....

Question 5. Has Safe Chain communicated with dispensers who have quarantined product? If so, what was the date and mode of communication?

Safe Chain stated "to our knowledge none of the customers still have any product in their inventory." FDA was looking for the 24 hour notification here....

Q5 is related to 4. Safe Chain was required to notify customers regarding that lot within 24 hours. The customer letter they provided FDA is dated 3/31/21 and pertains to Biktarvy lot 6400501A.

This was NOT one of the 5 lots Gilead identified. Yet Safe Chain's letter is from 3/31/21?

Question 6. Can Safe Chain assure that quarantined product that is still with dispensers will not be dispensed to consumers.

The answer Safe Chain provided conflicts with their answer in 5. Here Safe Chain states "No, those customers who did not respond to the letter(s) or request return of product could still have this in their possession or have already dispensed the drug."

As far as the Customer Letter- it does Not indicated that the product is illegitimate but just that here was a quality complaint (so does not meet DSCSA requirements). The lot # in the letter does not appear in the quarantine list- it is also not one of the lot #'s Gilead identified.

The list of suppliers Safe Chain provided to FDA still includes Gentek as active; it lists Blvd as inactive; list Mr. Unlimited as active. The list does not include Rapids or indicate "inactive." Further the list includes Gilead as a vendor.

I think we should get a call together with Safe Chain to discuss all this.

As far as quarantined inventory list. The lot # indicated in the Customer letter they provided to FDA does not appear on this list....

Safe Chain's compliance needed to show us all this before they responded to FDA.

Best,

Martha

Martha M. Rumore, PharmD, MS, JD, LL.M.
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From: Abbie Divilio <AbbieD@Safechain.com>

Sent: Friday, May 14, 2021 10:00 AM

To: Charles Boyd <CharlesB@Safechain.com>; Martha M. Rumore <mrumore@frierlevitt.com>; Pat Boyd <PatB@Safechain.com>; Anthony Berger <Tonyb@Safechain.com>

Cc: Jesse C. Dresser <jdresser@FrierLevitt.com>; Adam Brosius (Contact) <adam@pharmasales.com>

Subject: FDA communications

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Good morning,

Attached are the two most recent communications between Christina Picard and I regarding Gilead product.

Thanks,



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